

REMARKS

Claims 1, 6-12, 16-25 and 29-32 are presented in the case for consideration by the Examiner. Claims 10, 11, 17, 21 and 23 have been amended to more particularly define the invention. In particular as amended, the claims define a composite nonwoven product eminently suitably for medical applications because of its softness, ability to drape, ability to provide blood, bacterial and viral barrier protection, ability to maintain its integrity, i.e., not delaminate in a wet state, and ability to undergo ethylene oxide sterilization, these properties in fact being enhanced following ageing (see Tables 1-3). Basically as now defined in the claims, the nonwoven product of the invention comprises a composite of a cast film of at least two layers in which the two layers have different constituent parts, the multiple layer structure at its simplest having the structure AB, wherein A and B are different. This is laminated to one or more nonwoven substrates on one or both sides of the film using adhesives for the lamination. The makeup of the cast film is critical to the key properties of delamination (peel strength and in particular wet peel strength) and as a blood barrier following ethylene oxide sterilization and ageing, as is shown by the data provided by the applicants for example in Tables 1-3.

The Examiner has rejected claims 1-3, 6-12, 16-25 and 29-32, all of the claims in the case as being unpatentable (35 U.S.C. 103(a)) over Griesbach (2004/0123939) in view of Morman (2004/0091752), both published applications. It is the Examiner's position that Griesbach teaches the invention with the exception of the items noted, as for example "Griesbach does not teach the claimed amount of adhesive..." and "Griesbach fails to teach a barrier layer comprising low density polyethylene..." As to the former, the Examiner contends that the amount would be obvious, i.e., to optimize the amount of

dry adhesive would be within the routine skill of the artisan. As to the barrier layer, the Examiner relies on Morman as teaching a film comprising either LLDPE or LDPE where the film is employed in a laminate structure where liquid impermeability properties are desired.

It is emphasized that the nonwoven products of the invention first combine different polymers into different layers to form a multiple layer structure, i.e., cast film structure such as A-B, A-B-A, A-B-C, A-B-B-A (A, B and C are different polymers). To form the composite structure, the cast film is laid upon and laminated to one or more nonwoven substrates on one or both sides of the film.

The Griesbach published application relied on by the Examiner “is drawn to a laminate comprising a nonwoven web having been treated with a surfactant and a stretched film. The stretched film comprises a core layer and at least one skin layer. The core layer has a percentage by weight of a micropore developing filler material incorporated therein. The stretched film has been stretched in at least one direction to some percentage of its original size until a desired degree of vapor permeability is reached. The film is thermally bonded to the surfactant treated nonwoven. The end result is a laminate that forms both a breathable barrier and passes blood strikethrough in compliance with ASTM F1 670-95 and has an exposed face that is capable of absorbing aqueous liquids.” (page 2, paragraph [0014], underlining ours). Alternate embodiments disclosed by Griesbach all include the surfactant treated nonwoven web and thermal bonding. The properties, because of the different construct, are not akin to those disclosed by applicants. In fact, no improvement in peel strength, in particular wet peel strength, or ability to undergo ethylene oxide sterilization for example are disclosed or are they

possible because of the Griesbach construct. There is certainly no disclosure of wet peel strength being improved on ageing after sterilization in Griesbach.

More importantly, there is nothing in Griesbach to teach or suggest that the film layer comprises at least two layers, i.e., A-B wherein A and B are different polymers and certainly no teaching by Griesbach that the barrier layer be low density polyethylene.

Morman is directed to forming a film and laminate which are dynamic and namely, they are extendable in a cross-direction to a stretched width which is at least 25% greater than its original unstretched width. The two states of Morman film are again very different construct than the composite of the invention and in fact are not comparable to the barrier laminate of the invention since it is microporous. The term "microporous" is defined at paragraph [0024] of Morman and would interfere with obtaining the sought after properties of the instant application.

Morman at paragraph [0044] discloses the polymers which "include polyolefins, such as polyethylene, polypropylene, polybutene and the like, as well as olefin copolymers. Suitable olefin copolymers include copolymers having a major weight fraction (e.g. 70-99% by weight) ethylene and a minor weight fraction (e.g. 1-30% by weight) of a C₃-C₁₂ alpha-olefin comonomer. Such copolymers are commonly known as linear low density polyethylenes (where the density is about 0.900-0.935 grams/cm³) or very low density polyethylene (where the density is about 0.870 to less than 0.900 grams/cm³). Suitable olefin copolymers also include copolymers having a major weight fraction (e.g. 70-99% by weight) of a C₂ or C₄-C₁₂ alpha-olefin comonomer. The olefin polymer should be selected so that the film is extendible in the cross-direction, meaning that it can be stretched by at least 25% of its initial width without rupture or tear, and will

not retract by more than 30% of the difference between the stretched width and the initial width if the stretching force is removed. The key to selection of the polymer is that it be extendible as described. Morman continues for two additional paragraphs ([0045] and [0046]) with “other examples of extendible polymers.” The inventors in Morman have given what can best be defined as a shotgun disclosure. All of the polymers have the desired properties and the skilled in the art would have no reason to pick any one of them other than for availability, cost and the like. The polymer as used (polymer layer) would be microporous, include a plurality of voids and one or more filler particles in each void. If the Morman polymer was selected for incorporation into the Griesbach structure, it would be used as taught by Morman and Griesbach as well as with a micropore developing filler material incorporated therein and not unmodified. Further the Griesbach laminates all contain a surfactant so that they may become hydrophilic. A surfactant is not a requirement in producing the laminates claimed by the applicants herein.

The instant specification contains comparative data submitted for showing testing of the disclosed and claimed laminates and the results including realization of their desirable properties, i.e., wet peel strength and barrier properties. The criticality of the structure can be appreciated therefrom. The applicants submit herewith a declaration under 37 C.F.R. 1.132 for establishing the criticality and significant difference in results when the teachings of the invention are followed as compared to the teachings of the art.

The following table which is a composite of Tables 1 and 2 (page 11 and 12 of the application) and which is included in the declaration establishes the criticality of the claimed features. Thus as can be seen from the declaration, examples 1 and 3 which are A-B-A composites produce the desired wet/dry peel strength and barrier properties while

example 2 which is an A-A-A composite is much less satisfactory this being particularly noticeable after ageing.

| | | Example 1 | | | Example 2 | | | Example 3 | | |
|-------------------------------|-----------|-----------------------|-------------------------------|-------------------------|-----------------------|-------------------------------|-------------------------|-----------------------|-------------------------------|-------------------------|
| Date of Testing | Units | At time of production | After Aging (approx. 1 month) | After EtO Sterilization | At time of production | After Aging (approx. 1 month) | After EtO Sterilization | At time of production | After Aging (approx. 1 month) | After EtO Sterilization |
| Spunbond Weight (outer layer) | gsm | | 30 | | | 30 | | | 30 | |
| Spunbond Weight (inner layer) | gsm | | 20 | | | 20 | | | 20 | |
| Film Weight | gsm | | 18 | | | 18 | | | 18 | |
| Adhesive add-on (outer layer) | gsm | | 3 | | | 3 | | | 3 | |
| Adhesive add-on (inner layer) | gsm | | 2 | | | 2 | | | 2 | |
| Handelometer, MD | grams | | 89 | | | 86 | | | 87 | |
| Handelometer, CD | grams | | 41 | | | 47 | | | 44 | |
| Dry inner Peel Strength (CD) | g/in | 81 | 137 | 157 | 74 | 138 | 108 | 83 | 178 | 260 |
| Wet Inner Peel Strength (CD) | g/in | 97 | 193 | 179 | 90 | 37 | 34 | 117 | 267 | 375 |
| Blood barrier (ASTM F1670) | Pass/fail | pass | Pass | Pass | Pass | Pass | Pass | Pass | Pass | pass |

The results as contained in the declaration support the applicants' position that the invention is not obvious and would not have been foreseen by the skilled in the art.

Withdrawal of the rejection and allowance of the claims in the case are
respectfully requested.

Respectfully Submitted,
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